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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|--|-------------|----------------------|---------------------|------------------|
| 09/833,079 | 04/12/2001 | Peter O'Hanley | 050939-0104 | 1455 |
| 22428 | 7590 | 11/17/2003 | EXAMINER | |
| FOLEY AND LARDNER SUITE 500 3000 K STREET NW WASHINGTON, DC 20007 | | | FORD, VANESSA L | |
| | | | ART UNIT | PAPER NUMBER |
| | | | 1645 | |
| DATE MAILED: 11/17/2003 | | | | |

Please find below and/or attached an Office communication concerning this application or proceeding.

| Office Action Summary | Application No. | Applicant(s) | |
|------------------------------|------------------------|---------------------|--|
| | 09/833,079 | O'HANLEY ET AL. | |
| | Examiner | Art Unit | |
| | Vanessa L. Ford | 1645 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) Responsive to communication(s) filed on 28 July 2003.

2a) This action is **FINAL**. 2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4) Claim(s) 1-20 is/are pending in the application.

4a) Of the above claim(s) 4-7 is/are withdrawn from consideration.

5) Claim(s) _____ is/are allowed.

6) Claim(s) _____ is/are rejected.

7) Claim(s) _____ is/are objected to.

8) Claim(s) 1-3 and 8-20 are subject to restriction and/or election requirement.

Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) The proposed drawing correction filed on _____ is: a) approved b) disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) All b) Some * c) None of:

1. Certified copies of the priority documents have been received.
2. Certified copies of the priority documents have been received in Application No. _____.
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) The translation of the foreign language provisional application has been received.

15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) Notice of References Cited (PTO-892)
2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____

4) Interview Summary (PTO-413) Paper No(s). _____
5) Notice of Informal Patent Application (PTO-152)
6) Other: _____

DETAILED ACTION

1. Applicant's amendment and response filed July 28, 2003 is acknowledged. In view of Applicant's amendment, the following election of species is set forth.

Election of Species

2. This application contains claims directed to the following patentably distinct species of the claimed invention: The claims are drawn to an immunogenic composition and vaccine wherein the peptide is from a pilus type selected for the group consisting of F1, F1C, F8, F9, F10, F11, F12, F13, F71 and F72 serotypes. The following Table discloses the species that are encompassed by the claimed invention.

| Serotypes | Corresponding Sequences |
|-----------|---|
| F1 | SEQ ID NO:12 |
| F1C | SEQ ID NO: 11 |
| F8 | A SEQ ID NO as it corresponds to F8 is not disclosed in specification. |
| F9 | SEQ ID NOs: 7, 8 and 15 |
| F10 | A SEQ ID NO as it corresponds to F10 is not disclosed in specification. |
| F11 | SEQ ID NO:9 and 16 |
| F12 | SEQ ID NO:10 |
| F13 | SEQ ID NOs:1, 2 and 17 |
| F71 | SEQ ID NOs: 3, 4, 13 and 14 |
| F72 | SEQ ID NOs : 5 and 6 |

Applicant is asked to elected one serotype and the corresponding SEQ ID Nos: to be examined from the above table.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over

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the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

3. Any inquiry of the general nature or relating to the status of this general application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Papers relating to this application may be submitted to Technology Center 1600, Group 1640 by facsimile transmission. The faxing of such papers must conform with the notice published in the Office Gazette, 1096 OG 30 (November 15, 1989). Should applicant wish to FAX a response, the current FAX number for the Group 1600 is (703) 308-4242.

Any inquiry concerning this communication from the examiner should be directed to Vanessa L. Ford, whose telephone number is (703) 308-4735. The examiner can normally be reached on Monday – Friday from 7:30 AM to 4:00 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith, can be reached at (703) 308-3909.



Vanessa L. Ford
Biotechnology Patent Examiner
November 7, 2003



MARK NAVARRO
PRIMARY EXAMINER